

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,)	
)	
)	
Plaintiff,)	
)	Civil Action No.: 06-222 JJF
v.)	
)	
IMPAX LABORATORIES, INC.,)	
)	
Defendant.)	
_____)	

**REPLY MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION TO
MODIFY SCHEDULING ORDER**

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August 31, 2006

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I. INTRODUCTION

By its Motion to Modify the Scheduling Order, Defendant Impax Laboratories, Inc. (“Impax”) seeks a minor modification to the Court’s July 13 Scheduling Order that would move back to March 30, 2007 the deadline to request leave to amend pleadings. This modest modification will have no impact on the other pretrial dates set by the Court in the scheduling order and will not delay the time when this case may be brought to trial. There is good cause for the requested modification because Impax has been prejudiced by its inability to obtain relevant documents from Plaintiff Wyeth (“Wyeth”) prior to the August 10 deadline for amending pleadings. Moreover, setting the deadline to amend pleadings on the same date – March 30, 2007 – as the deadline for joinder of parties is logical and efficient because the decision regarding joinder of new parties requires the same sort of discovery needed to determine whether a present party has additional claims and defenses.

In its Answering Brief in Opposition to Impax’s motion, Wyeth spends many pages justifying its delay and refusal to produce documents prior to the August 10 deadline. All of these arguments do not change the simple fact that Impax did not, in fact, receive documents from Wyeth in time to investigate potential new counterclaims and defenses prior to the August 10 deadline for amending pleadings. Indeed, Impax still has not received more than a bare fraction of the documents it has requested from Wyeth. Wyeth makes no attempt to rebut the fact that the delay in document production and the inability to take fact depositions deprived Impax of the ability to plead all available claims and defenses. Nor can Wyeth articulate any prejudice it would incur if the deadline to amend pleadings were changed to a later date.

Because basic fairness dictates that this case should be adjudicated on the merits of fully developed claims and defenses, and not on an arbitrarily truncated record, there is good cause to modify the scheduling order to allow discovery and full investigation of potential defenses prior to any final deadline for amending the pleadings.

II. ARGUMENT

A. **There is good cause to change the deadline to amend pleadings to avoid prejudice to Impax.**

Wyeth's opposition brief is replete with justifications for delaying or refusing to produce documents before the August 10 deadline to amend pleadings. These arguments fail to address the main reason why postponing that deadline is justified here – to avoid prejudice to Impax. Setting aside the parties' disputes regarding Wyeth's document production obligations, it is undisputed that Impax only received a bare fraction of the documents it requested from Wyeth prior to the August 10 deadline. And Impax received *no documents* from Wyeth in time to meaningfully investigate potential new counterclaims and defenses prior to the August 10 deadline. All of this prejudice can be cured by postponing the deadline to amend pleadings to March 30, 2007, which is the deadline set by the Court to join new parties.

1. **Wyeth did not produce its NDA in time for meaningful analysis prior to the August 10 deadline.**

Wyeth only began its document production on August 4, just six days before the deadline to amend pleadings. On that day, Wyeth began a rolling production of its New Drug Application ("NDA") that did not conclude until August 8, just two days before the deadline to amend pleadings.¹ Declaration of Mary B. Matterer in Support of Impax's Motion to Modify the Scheduling Order and Motion to Compel ("Matterer Decl."), Ex.

¹ Wyeth did not *complete* the production of its NDA on August 8. On August 11, the day after the deadline to amend pleadings, Wyeth informed Impax that it would not produce "manufacturing records, specifications and analytical methods for venlafaxine hydrochloride itself, stability, toxicology, packaging, quality control, plant layouts and voluminous raw patient data" from its NDA. Reply Declaration of Mary B. Matterer In Support of Impax's Motion to Modify the Scheduling Order ("Reply Decl."), Ex. 1 at 2. There is, of course, no justification for this truncation of Wyeth's discovery obligations. Most of this information is highly relevant. For example, during patent prosecution, Wyeth distinguished prior art based on solubility of the drug. It is likely that solubility information is included in the manufacturing records, specifications, analytical methods, and other documents Wyeth is withholding.

23. Furthermore, portions of the NDA were mixed up and not produced in the way Wyeth would keep an important document in the ordinary course of business. As Wyeth points out in its opposition, this NDA consisted of 86,000 pages. Wyeth Br. at 8. There was no opportunity for Impax to meaningfully review the NDA before the deadline to amend pleadings. Impax has been prejudiced by its inability to review Wyeth's NDA in time to meet the August 10 deadline.²

2. Wyeth did not produce documents from the Teva Litigation in time for the August 10 deadline.

Wyeth produced *none of the documents* from its litigation on the patents-in-suit against Teva Pharmaceuticals (the "Teva Litigation") prior to the August 10 deadline, based on its assertion that "Teva has designated the bulk of this information as confidential and subject to the protective order in place in the Teva litigation, and it would be unduly burdensome to attempt to redact this information." Matterer Decl., Ex. 7 at 11, Ex. 8 at 26. As an attempt at compromise, Impax requested a limited subset of Teva Litigation documents by Friday, August 4, that clearly would not contain Teva confidential information: deposition transcripts of the inventors of Wyeth's patents-in-suit and 30(b)(6) witnesses and the Proposed Amended Answer submitted by Teva in support of a motion for leave to amend. Wyeth produced the requested transcripts on

² Subsequent review of the NDA has confirmed that it includes many documents that would have been helpful to Impax in researching and further developing counterclaims and defenses prior to the deadline to amend pleadings. For example, the NDA includes the raw data from the clinical studies cited by Wyeth in its patent specifications. Contrary to Wyeth's representations to the PTO, these studies failed to demonstrate an improved incidence of nausea and emesis in patients taking extended release formulations of venlafaxine in comparison with patients taking immediate release formulations. The NDA also contains articles about the cited studies confirming that there is no improved incidence of nausea and emesis in extended release formulations. Finally, the NDA contains data regarding drug solubility, which is pertinent to a potential new theory of inequitable conduct.

August 22, twelve days after the deadline to amend pleadings. Reply Decl., Ex. 2.³ Impax's inability to review these transcripts prior to the August 10 deadline for pleading amendments has deprived Impax of the ability to investigate potential new claims and defenses.

Furthermore, Wyeth has to this day failed to produce Teva's Proposed Amended Answer from the Teva Litigation. Wyeth's claim in its opposition brief that it cannot produce this Amended Answer because it contains Teva confidential information is demonstrably false. Teva moved to file its Proposed Amended Answer under seal in the Teva litigation because "[t]he materials that Defendants seek to seal include documents and information designated as confidential by *Plaintiff*," i.e., by Wyeth, not Defendant Teva. Matterer Decl., Ex. 20 ¶ 3 (emphasis added). Impax's inability to review this document, like many others, prior to the August 10 deadline has precluded a full investigation by Impax of its potential new counterclaims and defenses.

Finally, as of the filing of this brief, Wyeth has produced no other documents of the many relevant documents from the Teva Litigation, even though *Teva* agrees to their production. On August 22, Teva represented to Impax that, as to those documents containing Teva confidential information, Teva agrees to indicate to Wyeth material to be redacted and has "no objection to Wyeth's production of the redacted documents." Reply Decl., Ex. 3. Despite Teva's willingness to cooperate, Wyeth has recently declined to "produce 'all requested materials from the Teva litigation with only that [Teva confidential information] redacted.'" Reply Decl., Ex. 4 (quoting Reply Decl., Ex. 5) (brackets and emphasis in original). Again, Impax's inability to review documents from

³ It is now apparent that, as expected, the transcripts contain no Teva confidential information whatsoever. Wyeth's statement prior to the August 10 deadline that it would delay production of these transcripts until Teva confirmed this fact was mere pretext. Matterer Decl., Ex. 15 at 2, n.1.

the Teva Litigation prior to the August 10 deadline has prejudicially deprived Impax of the ability to investigate potential new claims and defenses.

3. Wyeth's unilateral limitations on discovery have deprived Impax of the ability to investigate potential claims and defenses prior to the August 10 deadline.

Apart from Wyeth's August 8 production of its 86,000-page NDA, Impax received no documents from Wyeth in time to investigate potential amendments to its pleadings prior to the August 10 deadline. This is because Wyeth has delayed and refused to produce documents by taking unreasonable and uncompromising positions. These discovery disputes are the subject of Impax's Motion to Compel, filed with the Court on August 10, 2006. (D.I. 36.) In summary:

- Wyeth refuses to produce responsive documents from its foreign facilities, even though Wyeth cites to at least one clinical study occurring overseas in its patent specifications and has prosecuted foreign equivalents to the patents-in-suit in numerous foreign countries. (D.I. 36 at 4.)
- Wyeth insists that it has no obligation to produce documents generated after February 10, 2003, more than three years before Wyeth filed suit, in contravention of Federal Rule of Civil Procedure 26(3)(2). (D.I. 36 at 4.)
- Wyeth refuses to produce documents in their native format, and will only produce documents with crucial and discoverable metadata stripped away, in contravention of Federal Rule of Civil Procedure 34 and Amended Federal Rule of Civil Procedure 26(b)(2)(B). (D.I. 36 at 2-3). Wyeth maintains this position even though it already possesses a database with objective coding that it readily could produce.
- Wyeth continues to insist that Impax pay for Wyeth's document productions. (D.I. 36 at 3.) Wyeth is, moreover, needlessly fanning the flames of this dispute by repeatedly asserting that Impax agreed to pay, even though Impax has informed Wyeth in no uncertain terms that **"because you have not produced any of the[] documents by August 4, 2006, which was the clear and unmistakable condition for our offer to pay for their production, we will not pay for their production."** Matterer Decl., Ex. 25 at 2 (emphasis in original); compare with Matterer Decl., Ex. 22 at 2 demanding reimbursement for the cost of document production based on "your July 31, 2006 agreement to reimburse").

The time and expense Impax has incurred in (a) negotiating with Wyeth to abate its unreasonable positions and (b) moving to compel on these issues, has deprived Impax of the ability to investigate potential new claims and defenses prior to the August 10 deadline.

Finally, Impax has been precluded from discussing any confidential Wyeth documents with its expert consultants prior to the August 10 deadline. Although Impax sent Wyeth a proposed stipulated protective order on July 12, 2006, Wyeth did not tell Impax whether it agreed to the proposed order until August 29, 2006 – seven weeks later. Reply Decl., Ex. 7; Reply Decl., Ex. 10 at 3. Over the past seven weeks Impax has sent repeated requests to Wyeth asking that it comment on the proposed order, but has yet to receive a substantive reply proposing modifications. *See, e.g.*, Reply Decl., Ex. 6 at 2, Ex. 7. Notably, on August 29, Wyeth informed Impax for the first time that it did not agree to the terms of the proposed order but failed to provide Impax with a revised version. Reply Decl., Ex. 10 at 3. Impax's inability to discuss confidential documents with its consultants prior to the deadline to amend pleadings has compounded the prejudice resulting from the failure to produce documents.

Wyeth's opposition brief presents absolutely no rebuttal to the simple fact that Impax's inability to receive discovery prior to the August 10 deadline has caused it prejudice. Indeed, Wyeth frankly admits that it does not feel obligated to produce documents until the October deadline for the close of document discovery. Wyeth Br. at 15 ("This Court entered its Scheduling Order on July 13, 2006, calling for document discovery to be completed in October, roughly two months after the deadline set for amendment of pleadings.") On the other hand, the prejudice to Impax can be cured by changing the August 10 deadline to March 30, 2007.

4. The prejudice to Impax will not be cured by imposing a heightened standard on Impax to move to amend.

Wyeth suggests that Impax would suffer no prejudice if the Court adheres to August 10 as the deadline to amend pleadings because “[s]hould Impax have good cause for a further amendment in the future, it can move for leave to amend at that time, *so long as it satisfies the requirements of Fed. R. Civ. P. 15 and 16(b).*” (D.I. 46 at 1) (emphasis added). Amendments to pleadings “shall be freely given when justice so requires.” FED. R. CIV. P. 15(a). By its reference to Rule 16, however, Wyeth is attempting to impose an additional “good cause” requirement to this liberal standard should Impax discover information to justify an amended pleading in the coming months.

This was the same strategy Wyeth pursued in the Teva Litigation when attempting to block Teva from pleading all of the defenses and counterclaims available to it. First, Wyeth delayed producing the bulk of its documents until near the close of document discovery – well after the deadline to amend pleadings in that case. Reply Decl., Ex. 8 at 3, figure (graph illustrating the pattern of Wyeth’s document productions). As it has done here, Wyeth produced less than 5% of its document production prior to the deadline to amend pleadings. *Id.* Then, when Teva moved to amend the pleadings after the deadline, Wyeth vigorously opposed that motion, and argued that Teva “was wrong to focus on the more liberal standard of Rule 15,” but must first satisfy the good cause requirement of Rule 16. Reply Decl., Ex. 9 at 11.⁴

Forcing Impax to meet a heightened standard in support of any motion to amend pleadings later this year or next will only enhance the prejudice Impax has incurred by Wyeth’s refusal to produce documents in timely fashion. Wyeth’s proposal that the parties re-brief this issue if Impax discovers information in support of an amended

⁴ Ultimately, the court denied the motion because it had been brought after the close of fact discovery. Matterer Decl., Ex. 4 at 4. Here, by contrast, Impax proposes that the deadline for amending pleadings take place well before the close of discovery.

pleading in the future would be highly inefficient, moreover, because it would force the Court to hear this issue multiple times.

B. Wyeth can articulate no prejudice it would incur if the deadline to amend pleadings were changed.

In contrast to the extreme prejudice that Impax would incur if the deadline to amend pleadings remains fixed on August 10, Wyeth has been able to articulate *no prejudice* that it would incur if the deadline were changed. Resetting this deadline would have no effect on any other case management date and would not delay the trial of this action. Under the proposed case schedule, Wyeth will have the same opportunity to investigate any new claims or defenses that Impax will have.

In short, there appears to be no reason for Wyeth to oppose this minor modification to the scheduling order other than to avoid a full and fair adjudication of all defenses and counterclaims available to Impax. This is contrary to the policy of the Federal Rules of Civil Procedure in favor of reaching a fair adjudication of cases on the merits. *Foman v. Davis*, 371 U.S. 178, 181 (1962) (“It is too late in the day and entirely contrary to the spirit of the Federal Rules of Civil Procedure for decisions on the merits to be avoided on the basis of such mere technicalities.”). Accordingly, the Court should modify the scheduling order to set the deadline to amend pleadings on March 30, 2007.

III. CONCLUSION

For the foregoing reasons, Impax respectfully requests that the Court modify the Scheduling Order to set March 30, 2007 as the deadline for amending pleadings.

Dated: August 31, 2006

/s/ Mary B. Matterer

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CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of August, 2006, I electronically filed the foregoing document, **REPLY MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION TO MODIFY SCHEDULING ORDER**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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